

DEXAJECT SP - dexamethasone sodium phosphate injection

Butler Animal Health Supply

PRODUCT TITLE(S) AND GENERAL WARNING/PRECAUTIONS

DEXAJECT SP

Dexamethasone Sodium Phosphate Injection, USP 4mg/mL

(equivalent to Dexamethasone 3mg/mL)

FOR INTRAVENOUS USE IN HORSES ONLY

WARNING: DO NOT USE IN HORSES INTENDED FOR FOOD

FOR VETERINARY USE ONLY

DESCRIPTION

Dexamethasone sodium phosphate (a synthetic adrenocortical steroid), is a white or slightly yellow crystalline powder. It is freely soluble in water and is exceedingly hygroscopic.

Each mL of sterile aqueous solution contains Dexamethasone Sodium Phosphate 4mg (equivalent to dexamethasone 3mg), Sodium Citrate 10mg, Sodium Bisulfite 2mg, Benzyl Alcohol 1.5% as preservative, in Water for Injection q.s. Sodium Hydroxide and /or Hydrochloric Acid to adjust pH to between 7.0 and 8.5.

CLINICAL PHARMACOLOGY

Dexamethasone is a synthetic corticosteroid and possesses glucocorticoid activity. Dexamethasone sodium phosphate is a salt of dexamethasone that is particularly suitable for intravenous administration because it is highly water soluble, permitting administration of relatively large doses in a small volume of diluent.

Dexamethasone, as a steroid, is equivalent in potency to some established steroids while being considerably more potent than others.

In the case of the dog, dexamethasone is found to be about equivalent in dosage to prednisone by about 30 to 40 times more potent than prednisolone.

INDICATIONS AND USAGE

Dexamethasone Sodium Phosphate Injection is indicated as a rapid adrenal glucocorticoid and/or anti-inflammatory agent in horses.

CONTRAINDICATIONS

Do not use in viral infections. Except when used for emergency therapy, dexamethasone sodium phosphate is contraindicated in animals with tuberculosis and chronic nephritis. Existence of congestive heart failure, osteoporosis and diabetes are relative contraindications.

In the presence of infection appropriate antibacterial agents should also be administered and should be continued for at least 3 days after discontinuance of the hormone and disappearance of all signs of infection.

WARNINGS

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced a cleft palate. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

PRECAUTIONS

Because of the anti-inflammatory action of corticosteroids, signs of infection may be hidden and it may be necessary to stop treatment until diagnosis is made. Overdosage of some glucocorticoids may result in sodium retention, fluid retention, potassium loss and weight gains.

In infections characterized by overwhelming toxicity, dexamethasone sodium phosphate therapy, in conjunction with indicated antibacterial therapy, is effective in reducing mortality. It is essential that the causative organism be known and an effective antibacterial agent be administered concurrently. The injudicious use of adrenal hormones in animals with infections can be hazardous.

Use of corticosteroids, depending on the dose, duration and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in unusually stressful situations.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ADVERSE REACTIONS

The therapeutic use of dexamethasone sodium phosphate injection is unlikely to cause undesired accentuation of metabolic effects.

However, if continued corticosteroid therapy is anticipated, a high protein intake should be provided to keep the animal in positive nitrogen balance. A retardant effect on wound healing should be considered when it is used in conjunction with surgery. Euphoria

or an improvement of attitude, and increased appetite are the usual manifestations. Side effects such as glycosuria, hyperglycemia, diarrhea, polydipsia and polyuria have been observed in some species.

Side effects such as SAP and SGPT enzyme elevations, eosinopenia, and vomiting have occurred following use of synthetic corticosteroids in dogs.

Cushing's Syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

Corticosteroids reportedly cause laminitis in horses.

DOSAGE AND ADMINISTRATION

For Intravenous Use Only.

Horses: the usual intravenous dosage is 2.5 to 5mg (based on 3mg per mL of dexamethasone content). If permanent corticosteroid effect is required, oral therapy with dexamethasone may be substituted. When therapy is to be withdrawn after prolonged corticosteroid administration, the daily dose should be reduced gradually over a number of days stepwise fashion.

HOW SUPPLIED

Dexamethasone Sodium Phosphate Injection 4mg/mL (equivalent to 3mg/mL dexamethasone) is available in 100mL multiple dose vials.

STORAGE

Store between 15 degree and 30 degree C (59degree - 86degree F).

Do Not Freeze.

CAUTION

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PACKAGE LABEL PRINCIPLE DISPLAY PANEL

NDC # 11695-4013-1

Butler Animal Health Supply

DexaJect SP

Dexamethasone Sodium Phosphate 4 mg Injection

4 mg per mL

Equivalent to dexamethasone 3 mg/mL

Sterile Multiple Dose Vial

For Intravenous Use in Horses Only


Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA 200-317, Approved by FDA

Net Contents: 100mL


Approved Art Copy
June 3, 2008

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ANADA #200-317 Approved by FDA
Net Contents: 100 mL
Distributed Exclusively by:
Butler Animal Health Supply • Dublin, OH 43017

Dosage: Usual intravenous dose for horses is 2.5 - 5 mg (based on 3 mg/mL Dexamethasone content).
See package insert for full information.
Warning: Do not use in horses intended for use in food.
FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN
Manufactured by: Bimeda-MTC Animal Health Inc.
Cambridge, Ontario, Canada N3C 2W4
Bimeda-MTC Animal Health Inc. is a Division of
Cross Vetpharm Group Ltd.
8DEX034
ISS.06.08

EACH mL CONTAINS: Dexamethasone Sodium Phosphate 4 mg (equivalent to Dexamethasone 3 mg), Sodium Citrate 10 mg, Sodium Bisulfite 2 mg with Benzyl Alcohol 1.5% as preservative in Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH.
Store between 15° and 30° C (59° and 86° F).
Do not freeze.
TAKE TIME  OBSERVE LABEL DIRECTIONS
Reorder #: 002458
System 39 Bar Code
4002458
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Value Based, Solutions Driven

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WARNINGS:
Clinical and experimental data have demonstrated that corticosteroids, when administered orally or by injection, may cause abortion in the first stage of pregnancy, fetal death, retained placenta, and stillbirth. Additionally, corticosteroids have produced cleft palates, phocomelia, and other anomalies in the offspring of dogs and cats receiving corticosteroids during pregnancy.